REMARKS/ARGUMENTS

This Amendment is responsive to the Office Action mailed on November 18, 2005. Applicant would like to thank the Petitions Examiner for granting Applicant's Request for Continued Examination and Applicant currently respectfully requests entry of this Amendment by the Examiner and reconsideration of the instant application in view of the following remarks:

Claims 19-25 are pending. Claims 19-25 are rejected.

Claims 19-25 remain in the application. Support for these Amendments is found on page 5, line154 to page 6, line169 of Applicant's specification.

Rejection under 35 U.S.C. §112 (First Paragraph)

Claims 19-25 are rejected as failing to comply with the written description requirement of 35 U.S.C. §112. The Examiner asserts that "Claim 19, part c is not described in the specification as filed." (Office Action, page2, ¶4) More specifically, the Examiner asserts that "only small particles are removed via the dip leg, not 'any undissolved portion'." *Id.* Applicant respectfully traverses.

Applicant submits that the term "undissolved" is described in the specification in a manner sufficiently clear as to enable one skilled in art to make and/or use the invention. On page 4, lines 108 - 109 of Applicant's Specification as filed, Applicant discloses "passing release medium through said cell such that **any undissolved portion** of the test sample is transferred out of the cell." Furthermore, on page 1 lines 21-31, Applicant discloses that an object of the present invention is to satisfy a need in the art relating to buccal dissolution tests. Applicant describes that "**undissolved components**, for example small particles, are removed from the mouth by swallowing so that their residence time is of the order of 5 - 60 seconds" and that "no current GI dissolution tests make allowance for removal of **undissolved components** from the test chamber" and "Applicants have invented a test method and apparatus that satisfies this need." Here Applicant clearly states that an object of the invention is to remove **undissolved** portions

or components in the dissolution tests. Small particles are included as merely a subset of undissolved components and do not act to exclude any other undissolved components.

Applicant respectfully submits that Applicant did in fact have possession of the claimed invention at the time the application was filed as demonstrated by the disclosure in the Specification and requests the Examiner withdraw the rejection of claims 19-25 under 35 U.S.C. § 112 (first paragraph).

Rejection under 35 U.S.C. § 112 (Second Paragraph)

The Examiner has rejected Claims 19-25 under 35 U.S.C. §112 (second paragraph) asserting that the claims are indefinite because Claim 19, part A) "can be continuously passed" is unclear. However, to expedite prosecution of claims 19-25, applicant is herein amending Claim 19, part A) to eliminate the "can be continuously passed language."

With respect to Claim 19, part C) as The Examiner appropriately noted in reason 4 of the Examiner's statement of reasons for allowance contained in the Notice of Allowability, mailed November 18, 2004 that "'small' is interpreted in view of the specification, see, eg., page 7, lines 214-221, in which the concept of 'small particles' is described relative to flow rates, tube size, and hydrodynamics."

Applicant respectfully submits that such amendment to Claim 19, part A) and current support in the Specification with respect to Claim 19, part C) renders the rejection of the claims under 35 U.S.C. § 112 (second paragraph) moot.

Rejection for Double Patenting

The Examiner has rejected Claims 19-25 under the judicially created doctrine of obvious-type double patenting as being unpatentable over Claims 1 and 3 of US 6,799,123. Applicant respectfully traverses. However, to expedite prosecution of Claims 19-25, the Applicants have amended the claims of the current invention to claim an in vitro buccal dissolution test. US 6,799,123 does not disclose, teach, or suggest an in vitro buccal dissolution test. One of ordinary skill in the art would not look to US 6,799,123

which discloses an in vivo dissolution test to perform an in vitro test on a living subject under physiologically relevant conditions.

Thus, Applicant respectfully submits that such amendment to Claims 19-25 renders the obvious-type double patenting rejection of the claims moot.

Rejection under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 19-25 as being unpatentable over Compton et al (US 4,594,902). Applicant respectfully traverses.

Applicant submits that the invention, as defined in amended claim 19 is a dissolution test, comprising the steps of:

a) **passing a release medium through a filtration cell having an outlet connected to a flow-through uv cell**;

b) **adding a test sample** to the filtration cell;

c) **passing the release medium through the cells such that any undissolved portion of the test sample is transferred out of the filtration cell;**

d) **removing samples of the release medium** from the flow-through uv cell, using the filtration cell such that the samples of the release medium do not contain any undissolved material;

e) maintaining the temperature of the flow-through uv cell at the desired temperature for the duration of the dissolution test;

f) analyzing the samples of the release medium from the flow-through uv cell to determine the concentration of substance dissolved from the test sample;

g) optionally, repeating the step of analyzing the samples of the release medium at multiple time during the duration of the dissolution test;

wherein the dissolution test is performed using apparatus comprising:

D) a supply of the release medium;

E) a means for transferring solid particles out of the filtration cell;

F) a means of mixing the sample and the release medium;

wherein the solid particles are of small particle size.

Applicant discloses passing a release medium through the filtration and flow through uv cells in order to ensure that all undissolved portions of the test sample are transferred out of the filtration cell which according to page 1 of the Specification, is primarily used to perform dissolution tests in the buccal cavity. There are unique problems associated with performing pharmaceutical dissolution tests in the buccal cavity such as: residence time and dissolution. Because the pharmaceutical is only in the buccal cavity for a few seconds it is desirable to have a test that can operate in shortened time intervals, eg. within minutes. Additionally as disclosed on page 1, when performing a buccal dissolution test for pharmaceuticals, incomplete buccal dissolution is preferable to mask the "objectionable taste" of most pharmaceuticals. Thus having a test which can simulate the conditions of the buccal cavity, like including a medium that can **quickly** separate the undissolved portion of the test sample from the dissolved portion to reveal how much of the sample actually dissolved, is critical. Applicant's invention as claimed uses the release medium to aid in effectuating this separation in a **quick and efficient** manner. **It is Applicant's test as claimed, by use of the release medium, which enables rapid test results.**

Compton et al fails to disclose, teach, or suggest Applicant's claimed invention because as the Examiner rightfully asserts, "Compton fails to explicitly teach passing a release medium through the cell or adding a test sample." (Office Action, page 4, ¶10). As aforementioned, the release medium in the present invention quickly (within minutes) separates the dissolved portions from the undissolved portions so that the test sample may be analyzed. Compton et al does not disclose a rapid test nor does it, as is the case in Applicant's invention, disclose a test which yields to a rapid results. Compton et al. disclose a dissolution test comparable to gastrointestinal dissolution tests, having a lengthy test period (hours). Compton et al disclose retrieving test samples over a period of 24 hours. Col. 1, lns 55-59. One of ordinary skill in the art would not look to Compton et al. for instructions on how to perform a buccal dissolution test in which analysis times are in the order of minutes by using a release medium.

In view of the above comments and observations, Applicants respectfully submit that the claimed invention is patentable over Compton et al.

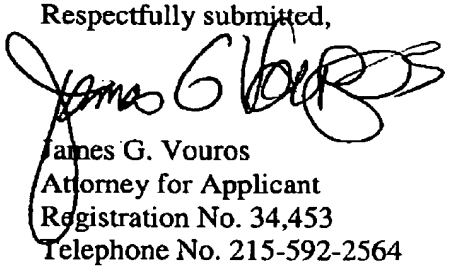
Accordingly, in view of the above amendments and remarks, it is respectfully requested that the Examiner withdraw the rejections and pass claims 19 to 25 to allowance at this time.

CONCLUSION

In view of the above Amendments and Remarks, Applicants believe that the pending claims, Claims 19-25, are in condition for allowance and Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Applicants hereby authorize the Commissioner to charge any fees which may be required or credit for overpayment for entry of this Amendment to Deposit Account No. 18-1850.

Respectfully submitted,



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